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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,152	06/20/2003	Sharon A. Baughman	P1775R1D1	5622

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
05/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,152	BAUGHMAN ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-18,20,21,24-28,31-37,86-90,92,94-97 and 99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4,7-11,13-18,29,31-33,37,86-90,92,94-99 and 2024* is/are allowed.

6)☒ Claim(s) *34 and 36* is/are rejected.

7)☒ Claim(s) *21 and 35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. The restriction between species of chemotherapeutic agent is withdrawn because there are no rejections of the claims over the prior art.

2. The amendment filed 2/9/2007 is acknowledged. Claims 5-6, 12, 19, 22, 23, 91, 93, 100, and 101 were canceled. Claims 1-4, 7-11, 12-18, 20, 21, 24-28, 31-37, 86-90, 92, 94-97 and 99 are pending and examined on the merits.

Claim Rejections Withdrawn:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The rejection of claims 9 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1-22, 27-29, 31-33, and 37 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating cancer characterized by overexpression of ErbB2 receptor, does not reasonably provide enablement for methods of treating a human patient susceptible to or diagnosed with a disorder characterized by overexpression of ErbB2 receptor, is withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. The rejection of claims 1-7, 9, 11-13, 23-27, 31-33, 86-97, 99, and 101 under 35 U.S.C. 102(e) as being anticipated by Sliwkowski (US 6,949,245; issued Sep. 27, 2005; effective filing date June 25, 1999) is withdrawn in view of applicants arguments showing that the provisional application supporting US 6,949,245 does not teach administration schedules where dosages are separated by 3 weeks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The rejection of claims 1-3, 5, 11, 17, 18, 22-29, 31, 32, 86-90, 92, 99, and 101 under 35 U.S.C. 103(a) as being unpatentable over Watanabe (Watanabe, T. et al., Proceedings of ASCO, 17: Abstract #702, 1998; cited in the IDS) in view of Seidman (Seidman, A.D. et al. Seminars in Oncology, 22(5): 108-116, 1995) and further in view of Baselga (Baselga, J. et al., Proceedings of the American Association for Cancer Research, 35: 380, Abstract #2262, 1994) is withdrawn in view of the amendment which limits the claimed methods to methods where the between administration of the subsequent doses is at least 2 weeks.

7. The rejection of claims 1, 5, 22-29, 31, 32, and 101 under 35 U.S.C. 103(a) as being unpatentable over either Baselga-1994 (Baselga, J. et al Breast Cancer Research and Treatment, 32(suppl): page 30, Abstract #5, 1994) or Baselga-1996 (Baselga, J. et al., Journal of Clinical Oncology, 14(3): 737-744, 1996; cited in the IDS) in view of Seidman (Seidman, A.D. et al. Seminars in Oncology, 22(5): 108-116, 1995) and further in view of Baselga (Baselga, J. et al., Proceedings of the American Association for Cancer Research, 35: 380, Abstract #2262, 1994) is withdrawn in view of the amendments to the claims which limits the claimed methods to methods where the between administration of the subsequent doses is at least 2 weeks.

New Grounds of Rejection:

8. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 fails to further limit the subject matter of claims 1, from which it depends, because claim 1 recites that the subsequent doses are separated in time from each other by at least two weeks, whereas, in claim 21, the subsequent doses appear to be separated in time by at least one week.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 34 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is that the specification fails to adequately describe the genus of "anthracycline derivative".

Claims 34 and 36 are drawn to methods comprising administering and anti-ErbB2 antibody in combination with an anthracycline derivative, and possibly further comprising administration of a cardioprotectant (claim 36). The phrase "anthracycline derivative" is interpreted as referring to a genus of compounds that has been "derived" from an anthracycline. The term "derived" or "derivative" implies that the agent referred to in the claims may be a compound that comprises a part of an anthracycline. The specification contains no definition of the phrase "anthracycline derivative", and provides only the teachings of two examples, doxorubicin and epirubicin, which are anthracyclines, not "anthracycline derivatives".

For a claim drawn to a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one

must describe a sufficient variety of species to reflect the variation within the genus (see Official Gazette 1241 OG 174, January 30, 2001).

Because the claims are drawn to administration of "anthracycline derivatives", the claims are drawn to methods comprising the administration of any compound that would be encompassed by the phrase "anthracycline derivative". The broadest reasonable interpretation of the phrase "anthracycline derivative" is that it refers to a genus of molecules that comprises parts of anthracyclines, and that the parts may be as small as one molecules. Thus, the phrase "anthracycline derivative" encompasses a genus of molecules that are not described in the specification by a representative number of species or by a disclosure of relevant, identifying characteristics. Therefore, the claimed methods are not adequately described because the genus of compounds which are to be administered are not adequately described.

Conclusion

Claims 1-4, 7-11, 13-18, 20, 24-29, 31-33, 37, 86-90, 92, 94-99 are allowable. Claims 21 and 35 are objected to. Claims 34 and 36 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
April 30, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER